UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,746	02/18/2004	Sheldon B. Greer	2954-128	2050

6449 7590 05/09/2006

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,746	GREER, SHELDON B.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a method of treating tumors with a combination of agents (*e.g.* 5-chloro-2'-deoxycytidine and a acytidine deaminase inhibitor), classified in class 514, subclass 49.

II. Claims 14-20, drawn to a method of hypomethylating genes (*e.g.* 5-chloro-2'-deoxycytidine and a acytidine deaminase inhibitor), classified in class 514, subclass 49.

III. Claim 21, drawn to a composition comprising 5-chloro-2'-deoxycytidine and 4-*N*-methylamino FdC, classified in class 514, subclass 49.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are directed to related methods using similar compositions. The related inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.*, are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method claims of Group I have a materially different function and effect than the claims of Group II. The method of Group II is intended to be used to "turn on" silenced tumor-suppressor genes of tumors susceptible to hypomethylation. The

method claims of Group I, although utilizing the same composition as the method claims of Group II, require that tumors be treated with radiation after administering the tumor-treating agents. The use of radiation to treat tumors is not required by the method steps of Group II. Further, the method steps of Group II could be used for a materially different function (*e.g.* to investigate the presence or absence of silenced genes in animal tumor models of various cancers).

Groups III and I/II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the processes for using the product as claimed can be practiced with another materially different product. For example, other hypomethylating agents (*e.g.* 5-azacytidine, N6-benzyladenine, etc.) could be used in the method steps of Group II. The method steps of Group I could be practiced with agents capable of shifting the hemoglobin (Hb)-O_2 dissociation curve to the right (decreased Hb affinity), thereby sensitizing tumors to radiation by reducing the fraction of radiobiologically hypoxic cells.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Specie Election Requirement for Either Group I or Group II

This application contains claims directed to the following patentably distinct species: multiple combinations of agents for sensitizing tumors to irradiation and/or for hypomethylating genes. If applicant elects Group I or Group II, applicant is further required to elect a single enhanced drug combination for prosecution on the merits. The drug combinations are independent or distinct because a search for one combination of agents would not be the same as a search for a different combination of agents. For example, a search for a composition comprising 5-chloro-2'-deoxycytidine, 1-β-ribofuranocyl-1,2-dihydropyrimidin-2-one (Zebularine), and 4-N-methylamino FdC for treating tumors would not be the same as a search for a composition comprising 5-chloro-2'-deoxycytidine and tetrahydrouridine.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed enhanced drug combination for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 2, and 7-13 (Group I) and 14, 19, and 20 (Group II) are generic.

Applicant is advised that a reply to this requirement must include an identification of the combination of agents (*e.g.* 5-chloro-2'-deoxycytidine, 1-β-ribofuranocyl-1,2-dihydropyrimidin-2-one (Zebularine), and 4-N-methylamino FdC), including a specific cytidine deaminase inhibitor, that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. If no cytidine deaminase inhibitor is elected, all claims drawn to methods that include compositions comprising a cytidine deaminase inhibitor will be withdrawn from further

consideration as being drawn to a non-elected invention. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James D. Anderson
Examiner
Art Unit 1614

JDA
May 1, 2006

Ardin H. Marschel 5/5/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER